APPENDIX B

1. (Once Amended) A hydrogel comprising less than 3.5% polyacrylamide by weight, based on the total weight of the hydrogel, said hydrogel obtainable by combining acrylamide and methylene bis-acrylamide, under conditions of radical initiation, and washing with pyrogen-free water or saline solution; said hydrogel being biocompatible[; and said combining being in a molar ratio of 150:1 to 1000:1)].

5. (Once Amended) A hydrogel according to claim 2, comprising at least 0.5% by weight [, such as at least 1%, preferably at least 1.5%] polyacrylamide, [such as at least 1.6% polyacrylamide by weight,] based on the total weight of the hydrogel.

6. (Once Amended) A hydrogel according to claim 2, which [characterised in that it] has complex viscosity not less than 2 Pas [, such as not less than 3, 4 or 5 Pas].

7. (Once Amended) A hydrogel according to claim 2, which [characterised in that it] has complex viscosity from about 2 to 90 [, such as 5 to 80 Pas, preferably from about 6 to 76, such as from about 6 to 60, 6 to 40, 6 to 20, such as 6 to 15] Pas.

8. (Once Amended) A hydrogel according to claim 2, which [characterised in that it] has elasticity module of not less than 10 Pa [, such as not less than 20, 25, 30, 31, 32, 33, 34 or 35 Pa, such as not less than 38 Pa].

9. (Once Amended) A hydrogel according to claim 2, which [characterised in that it] has elasticity module from about 10 to 700 Pa [, such as about 35 to 480 Pa].

10. (Once Amended) A hydrogel according to claim 2, which includes [characterised in that] the cross-linked polyacrylamide [is] to such a [as] degree so as to have an efficient cross-linking density of about 0.2 to 0.5% [, preferably about 0.25 to 0.4%].

11. (Once Amended) A hydrogel according to claim 1, wherein the acrylamide and methylene bis-acrylamide are combined in the molar ratio of from [is] 175:1 to 800:1 [, such as from 225:1 to 600:1, preferably from 250:1 to 550:1, most preferably from 250:1 to 500:1].

12. (Once Amended) A hydrogel according to claim 3, wherein the implantable endoprosthesis [optionally] comprises a silicone-based envelope housing the hydrogel.

15. (Once Amended) An endoprosthesis according to claim 13 further comprising cells [, such as stem cells, for cellular engraftment].

16. (Once Amended) A method for the preparation of a hydrogel comprising the steps of combining acrylamide and methylene bis-acrylamide, under conditions of radical initiation, and washing with pyrogen-free water so as to give less than 3.5% by weight polyacrylamide, based on the total weight of the polyacrylamide.

17. (Once Amended) The method according to claim 16, wherein the hydrogel comprises at least 1.5% polyacrylamide [, such as at least 1.6% polyacrylamide] by weight, based on the total weight of the hydrogel.

19. (Once Amended) The method according to claim 16, wherein the washing step comprises swelling the product of the radical initiation step until the elasticity module is from about 10 to 700 Pa [, from about 35 to 480 Pa].

20. (Once Amended) The method according to claim 16, wherein the washing step comprises swelling the product for 50 to 250 hours [, more typically for 70 to 200 hours].

22. (Once Amended) The method according to claim 21, wherein the ratio of acrylamide to methylene bis-acrylamide is about 175:1 to 800:1 [, such as about 225:1 to 600:1, preferably about 250:1 to 550:1, most preferably about 250:1 to 500:1].

23. (Once Amended) A method of treatment of a cosmetic or functional defect with an injectable or implantable biocompatible endoprosthesis comprising:

a) [preparation of] preparing a polyacrylamide hydrogel, said polyacrylamide hydrogel comprising less than 3.5% by weight of polyacrylamide and said polyacrylamide being cross-linked [using] with methylene bis-acrylamide,

b) [injection] injecting or [implantation] implanting a sufficient amount of said polyacrylamide hydrogel into a region of the body affected by a cosmetic or functional defect.

24. (Once Amended) The method of treatment according to claim 23, wherein the polyacrylamide hydrogel comprises at least 0.5% polyacrylamide by weight, based on the total mass of the hydrogel [, such as at least 1%, such as at least 1.5%, such as at least 1.6% polyacrylamide by weight, based on the total mass of the hydrogel].

25. (Once Amended) The method according to claim 23, wherein the preparation of the polyacrylamide hydrogel is according to the method defined in claim 16.

26. (Once Amended) The method according to claim 23, wherein the endoprosthesis is used for mammoplastic reconstruction or augmentation, treating reflux oesophagitis, body contouring, [and] or penis enlargement.

28. (Once Amended) The method according to claim 26, wherein the hydrogel comprises less than 1.6% polyacrylamide by weight, based on the total weight of the hydrogel, and wherein the endoprosthesis for mammoplastic reconstruction is implantable, said endoprosthesis [optionally] further comprising a silicone-based envelope.

29. (Once Amended) The [hydrogel] method according to claim 23, wherein the polyacrylamide hydrogel comprises at least 1% by weight polyacrylamide, based on the total weight of the hydrogel.

30. (Once Amended) A method of cosmetically altering a mammalian breast or of performing a partial or total mammoplastic reconstruction on a woman comprising implanting a polyacrylamide hydrogel endoprosthesis; wherein said polyacrylamide hydrogel endoprosthesis comprises: i) more than 9.5% polyacrylamide by weight, based on the total weight of the hydrogel, and ii) at least 75% pyrogen-free water or saline solution.

31. (Once Amended) The method according to claim 30, wherein the polyacrylamide hydrogel endoprosthesis comprises less than 25% by weight polyacrylamide, based on the total weight of the hydrogel [, such as less than 20%].

33. (Once Amended) A method according to claim 23 comprising augmenting the size of a penis comprising the administration to the penis of a polyacrylamide

hydrogel, wherein the polyacrylamide hydrogel comprises less than 3.5% polyacrylamide by weight, based on the total weight of the hydrogel.

34. (Once Amended) The method according to claim 33, wherein the polyacrylamide hydrogel further comprises at least 95% pyrogen-free water or saline solution.

35. (Once Amended) The method according to claim 33, wherein the administration is by means of injection into a cavernous tissue.

36. (Once Amended) A method of augmenting the size of a penis comprising the implantation of a polyacrylamide hydrogel endoprosthesis wherein the polyacrylamide hydrogel endoprosthesis comprises i) more than 9.5% polyacrylamide by weight, and ii) pyrogen-free water or saline solution.

37. (Once Amended) The method according to claim 36, wherein the polyacrylamide hydrogel endoprosthesis has a complex viscosity of at least 10 [Pa.s] Pa s
[, such as at least 15 Pa s, preferably at least 20 Pa s, more preferably at least 30 Pa s, most preferably at least 40 Pa s].

38. (Once Amended) A method of cosmetically altering a mammalian body (body contouring) comprising implanting a polyacrylamide hydrogel endoprosthesis, wherein the polyacrylamide hydrogel endoprosthesis comprises i) more than 9.5% polyacrylamide by weight, based on the total weight of the hydrogel, and ii) pyrogen-free water or saline solution.